5000 Series with Auditor Features

Data Management with 21 CFR Part 11 in Mind

Auditor features on the 5000 recorders have been specifically designed to meet the requirements of the FDA 21 CFR Part 11 document for Electronic Records and Electronic Signatures.   Data is held in Human Readable and Electronic Record. Electronic data can be viewed, analysed and printed off-line using the secure Review package

Data security is paramount for FDA approved processes - 5000 products ensure that data is not lost or tampered with. Their Auditor Software features provide comprehensive security and traceability

Secure Audit Trails   Electronic Signing   Password Aging   Timed Logout   Recorded Logins   Password Retries

Secure Audit Trails

A secure, product-generated, time-stamped audit trail to record the date and time, operator details and actions taken on the recorder. The Audit Trail is kept with the electronic process data, records all actions and cannot be separated from the process data, removed or modified.

Electronic Signing

Auditor features allow for signing of all actions - operator will need to re-enter user name and password before action is complete. Recorder can also be made to request authorisation - a second signature - before the action is completed.

Signed Operator Comments

An authorised operator is able to add comments to the data record by entering their correct user name and password followed by the required text. The full comment complete with the operator name, date and time is recorded in the data file to become an integral part of the data record.

Signature Element Controls

Passwords will automatically expire unless renewed within a set time. All standard user logins can be disabled and their associated passwords removed to prevent any unauthorised access.

User accounts are disabled after a selectable number of failed attempts to log in.
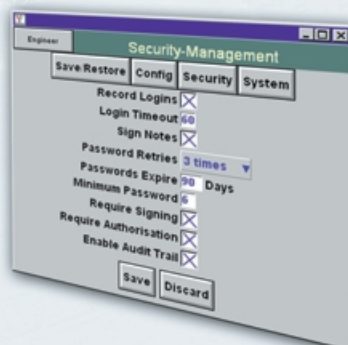
Passwords can be forced to be a minimum length.

Operators will be automatically logged out after a pre-defined period of inactivity

Recorded Logins

Every time an operator logs in user name, date and time are recorded into the Audit Trail.

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Additional Security Features

- **Enforced Unique Signatures**
  Each user can have a unique set of access permissions to customise what they can do on the product. Each user name is unique and passwords are individual and cannot be view on the product. User ID cannot be duplicated and each user name must be unique within the product.

- **Protection of Records – Secure, Reliable, Accurate Records**
  Data is stored in a binary, compressed and checksum format proprietary to Eurotherm Ltd to protect from tampering with records.

- **Device Checks for Validity of Inputs**
  5000 logs system errors and input channel status. Remote operator access can be enabled or disabled on an individual user basis.

Additional Features

- **6 to 48 universal inputs**
- **Up to 27 changeover relay outputs**
- **Multi-batch recording**
- **Barcode Reader serial input**
- **Standard Networking via Ethernet**
- **FTP Client & Server**
- **Modbus TCP**
- **Time Synchronisation via Ethernet (SNTP) or digital input**
- **Maths functions, Totalisers, Timers and Counters**
- **Message Log and Alarm Summary Page**
- **Screen Builder software - user defined screen views**
- **Bridge Software – Remote viewing, configuring and operating software – via LAN, intranet or Internet**
- **Batch – Up to 6 user-defined batch fields to enter batch specific information on start and/or end of batch**
- **Adaptive Recording – record maximum and minimum values between recording intervals**

Sales and support in over 30 countries worldwide